Art Unit: 1641

DETAILED ACTION

1. Applicant's amendment filed 12 April 2007 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1, 2, 5-7, 10, 11, 20, 21, 24, 25, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang et al. (US 5,559,041) in view of Catt et al. (US 6,451,619) further in view of Yu (US 6,723,500).

Kang et al. teach a device comprising one or more dry porous membranes, wherein the membranes provide a membrane channel through which the liquid sample can flow by capillary action while reactions take place to determine at least one component in the sample (col. 4, lines 47-38; col. 4, lines 50-65); wherein the platform is formed with sample application means, holds the membrane in place and forms a flow channel upstream of the membrane, the formed channel being in communication with the membrane to permit the liquid to flow in a continuous pathway from the sample application means to the distal end of the membrane (col. 4, lines 50-54). Kang et al. fail to teach the platform formed by face

to face contact of a top and bottom layer having a bottom and top hydrophilic surface, respectively and an indent in at least one of the hydrophilic surfaces.

Catt et al. teach a test strip (204, Fig. 2) mounted in a plastic platform that has a top and bottom layer (top layer, 200, bottom layer, 201, Fig. 2; col. 23, lines 25-44) to enclose and position a membrane so that the bottom surface of the top layer and the top surface of the bottom layer are brought into fixed face to face contact to enclose the membrane in place and including an indent in the bottom surface of the top layer to form a channel to hold the membrane (Fig. 2; col. 23, lines 25-44), in order to provide a good moisture conducive junction between porous membranes. Catt et al. fail to specifically teach the plastic platform being hydrophilic.

Yu teaches a channel that is hydrophilic wherein a hydrophilic matrix may be placed inside the channel (one or more of the embodiments would include a hydrophilic channel wherein a hydrophilic matrix is within the channel, col. 11, lines 32-56), in order to provide sample flow through the channel.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the platform of Kang et al., a platform having a top and bottom layer that are placed in face to face contact to hold the membrane in place with an indent in the bottom surface of the top layer to form a channel as taught by Catt et al., in order to provide a test strip casing that is inexpensive to produce and easy to assemble. It would have further been obvious to one having ordinary skill in the art at the time the invention was made to include in the platform of Kang et al. in view of Catt et al., the plastic platform surfaces forming the channel being hydrophilic as taught by Yu, in order to provide an accurate, precise and efficient test strip wherein sample is moved quickly through a channel.

With respect to claims 5, 10 and 24, Kang et al. teach a window in the top of the device for observing the results of a reaction which takes place in the membrane (col. 4, lines 50-56) and Catt et al. teach a window in the top layer of the device (col. 23, lines 34-39).

Regarding claims 11 and 25, Kang et al. teach that a plurality of reagents may be present for detecting one or more analyte (col. 5, lines 1-11).

With respect to claim 20, Kang et al. teach the device containing an upstream detection membrane and a downstream capture membrane (filter elements and wicking membrane, col. 4, lines 20-38; col. 3, lines 50-61), wherein the detection membrane constructed to filter unwanted components from the sample and containing a mobile labeled detection region which will react with the component to form a reaction product which moves downstream in the detection membrane (although Kang does not specifically teach removing red blood cells, the filter is capable of removing red blood cells if the cells are the unwanted components, col. 3, lines 24-42); a capture membrane downstream of the detection membrane and containing a fixed, immobile capture reagent which will react with and concentrate the reaction product at a capture line (col. 3, lines 50-60), the downstream end of the detection membrane slightly overlapping the upstream end of the capture membrane (col. 5, lines 45-53); the membranes being enclosed in a platform (described above in the explanation of obviousness over Kang et al. in view of Catt et al. further in view of Yu) wherein the sample flows in a continuous path from the application means through the detection membrane to the distal end of the capture membrane (col. 4, lines 50-65).

Regarding claim 33, Kang et al. teach the detection membrane being a glass fiber membrane (col. 6, lines 32-35) and the capture membrane being a nitrocellulose membrane (wicking membrane, col. 6, lines 38-42).

With respect to claim 34, Kang et al. teach the membranes covered with a transparent cover layer (col. 7, lines 23-25).

Regarding claim 35, Catt et al. teach the porous material sandwiched between two transparent layers of polyester film (col. 25, line 63-col. 26, line 5).

3. Claims 1, 2, 5-7, 10, 11, 20, 21, 24, 25, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang et al. (US 5,559,041) in view of Catt et al. (US 6,451,619) further in view of Segal et al. (US 6,300,141).

Kang et al. teach a device comprising one or more dry porous membranes, wherein the membranes provide a membrane channel through which the liquid sample can flow by capillary action while reactions take place to determine at least one component in the sample (col. 4, lines 47-38; col. 4, lines 50-65); wherein the platform is formed with sample application means, holds the membrane in place and forms a flow channel upstream of the membrane, the formed channel being in communication with the membrane to permit the liquid to flow in a continuous pathway from the sample application means to the distal end of the membrane (col. 4, lines 50-54). Kang et al. fail to teach the platform formed by face to face contact of a top and bottom layer having a bottom and top hydrophilic surface, respectively and an indent in at least one of the hydrophilic surfaces.

Catt et al. teach a test strip (204, Fig. 2) mounted in a plastic platform that has a top and bottom layer (top layer, 200, bottom layer, 201, Fig. 2; col. 23, lines 25-44) to enclose and position a membrane so that the bottom surface of the top layer and the top surface of the bottom layer are brought into fixed face to face contact to enclose the membrane in place and including an indent in the bottom surface of the top layer to form a channel to hold the membrane (Fig. 2; col. 23, lines 25-44), in order to provide a good moisture conducive junction between porous membranes.

Segal et al. teach a channel comprising a hydrophilic porous material (col. 13, lines 21-25; col. 12, lines 23-40) wherein the channel is made out of the substrate material which is a non-porous rigid, moisture impermeable material of either polystyrene or glass (col. 9, lines 6-21), in order to provide sample flow through the channel.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the platform of Kang et al., a platform having a top and bottom layer that are placed in face to face contact to hold the membrane in place with an indent in the bottom surface of the top layer to form a channel as taught by Catt et al., in order to provide a test strip casing that is inexpensive to produce and easy to assemble. It would have further been obvious to one having ordinary skill in the art at the time the invention was made to include in the platform of Kang et al. in view of Catt et al., the platform surfaces forming the channel being glass, which is a hydrophilic material as taught by Segal et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent substrate material and since the same fluid transport and device structure would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

With respect to claims 5, 10 and 24, Kang et al. teach a window in the top of the device for observing the results of a reaction which takes place in the membrane (col. 4, lines 50-56) and Catt et al. teach a window in the top layer of the device (col. 23, lines 34-39).

Regarding claims 11 and 25, Kang et al. teach that a plurality of reagents may be present for detecting one or more analyte (col. 5, lines 1-11).

With respect to claim 20, Kang et al. teach the device containing an upstream detection membrane and a downstream capture membrane (filter elements and wicking

membrane, col. 4, lines 20-38; col. 3, lines 50-61), wherein the detection membrane constructed to filter unwanted components from the sample and containing a mobile labeled detection region which will react with the component to form a reaction product which moves downstream in the detection membrane (although Kang does not specifically teach removing red blood cells, the filter is capable of removing red blood cells if the cells are the unwanted components, col. 3, lines 24-42); a capture membrane downstream of the detection membrane and containing a fixed, immobile capture reagent which will react with and concentrate the reaction product at a capture line (col. 3, lines 50-60), the downstream end of the detection membrane slightly overlapping the upstream end of the capture membrane (col. 5, lines 45-53); the membranes being enclosed in a platform (described above in the explanation of obviousness over Kang et al. in view of Catt et al. further in view of Segal et al.) wherein the sample flows in a continuous path from the application means through the detection membrane to the distal end of the capture membrane (col. 4, lines 50-65).

Regarding claim 33, Kang et al. teach the detection membrane being a glass fiber membrane (col. 6, lines 32-35) and the capture membrane being a nitrocellulose membrane (wicking membrane, col. 6, lines 38-42).

With respect to claim 34, Kang et al. teach the membranes covered with a transparent cover layer (col. 7, lines 23-25).

Regarding claim 35, Catt et al. teach the porous material sandwiched between two transparent layers of polyester film (col. 25, line 63-col. 26, line 5).

4. Claims 12, 13 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang et al. (US 5,559,041) in view of Catt et al. (US 6,451,619) further in view of Segal et al. (US 6,300,141), as applied to claims 6 and 20, and Freitag et al. (US 6,214,629).

Kang et al. in view of Catt et al. further in view of Segal et al. teach a device comprising reagents for analyte detection, but fail to teach the analyte being Troponin I.

Freitag et al. teach reagents for the detection of Troponin I in a chromatographic assay (col. 9, line 63-col. 10, line 21), in order to provide detection of cardiac analytes.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Kang et al. in view of Catt et al. further in view of Segal et al., reagents in a porous material for the detection of Troponin I in a blood sample as taught by Freitag et al., in order to provide diagnosis for the cause of chest pain and to determine a cardiac event.

5. Claims 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang et al. (US 5,559,041) in view of Catt et al. (US 6,451,619) further in view of Yu (US 6,723,500), as applied to claims 1, 6 and 20, and Deng (US 6,740,293).

Kang et al. in view of Catt et al. further in view of Yu teach a device comprising a top surface and bottom player in fixed face to face contact to form a flow channel, but fail to teach open areas to inhibit flow into space between the top and bottom layers and protrusions in the top layer that mate with indents in the bottom layer.

Deng teaches a device comprising platform with a top layer (13, Fig. 7) and a bottom layer (12, Fig. 7), wherein the top layer and bottom layer comprise a flow channel having a test strip (col. 6, line 59-col. 7, line 3) wherein the top and bottom layers have open areas, which inhibit flow from the platform flow channel into space between the surfaces of the top and bottom layers (flow is limited to the porous strip, col. 9, lines 19-28; space is between side wall of 12 and test strip 19, which prevents flow between 12 and 13 when they are sealed; openings are created to prevent flow from creeping into handle section, which is between top and bottom layers, col. 7, lines 44-54) and the top surface of the lower layer comprising cylindrical pillars (11a, Fig. 8) that register with cylindrical indents (11b, Fig. 8;

col. 6, lines 14-22), in order to provide secure snapping and prevent leaking between the top and bottom layers.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the platform of Kang et al. in view of Catt et al. further in view of Yu, cylindrical pillars that register with indents and open areas that inhibit flow of the sample between the top and bottom layers as taught by Deng, in order to provide sufficient sealing and prevent leaking outside of the device.

Deng fails to teach the protrusions being rectangular. However, it would have been obvious to one having ordinary skill to provide a different shape to perform the same function of snapping the top and bottom layers together. In re Dailey et al. 149 USPQ 47 (C.C.P.A. 1966).

6. Claims 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang et al. (US 5,559,041) in view of Catt et al. (US 6,451,619) further in view of Segal et al. (US 6,300,141), as applied to claims 1, 6 and 20, and Deng (US 6,740,293).

Kang et al. in view of Catt et al. further in view of Yu teach a device comprising a top surface and bottom player in fixed face to face contact to form a flow channel, but fail to teach open areas to inhibit flow into space between the top and bottom layers and protrusions in the top layer that mate with indents in the bottom layer.

Deng teaches a device comprising platform with a top layer (13, Fig. 7) and a bottom layer (12, Fig. 7), wherein the top layer and bottom layer comprise a flow channel having a test strip (col. 6, line 59-col. 7, line 3) wherein the top and bottom layers have open areas, which inhibit flow from the platform flow channel into space between the surfaces of the top and bottom layers (flow is limited to the porous strip, col. 9, lines 19-28; space is between side wall of 12 and test strip 19, which prevents flow between 12 and 13 when they are sealed; openings are created to prevent flow from creeping into handle section, which is

between top and bottom layers, col. 7, lines 44-54) and the top surface of the lower layer comprising cylindrical pillars (11a, Fig. 8) that register with cylindrical indents (11b, Fig. 8; col. 6, lines 14-22), in order to provide secure snapping and prevent leaking between the top and bottom layers.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the platform of Kang et al. in view of Catt et al. further in view of Segal et al., cylindrical pillars that register with indents and open areas that inhibit flow of the sample between the top and bottom layers as taught by Deng, in order to provide sufficient sealing and prevent leaking outside of the device.

Deng fails to teach the protrusions being rectangular. However, it would have been obvious to one having ordinary skill to provide a different shape to perform the same function of snapping the top and bottom layers together. In re Dailey et al. 149 USPQ 47 (C.C.P.A. 1966).

Response to Arguments

1. Previous rejections under 35 USC 112, second paragraph have been withdrawn in light of applicant's amendments.

2. Applicant's arguments filed 12 April 2007 regarding the rejections under 35 USC 103a have been fully considered but they are not persuasive.

3. Regarding the rejections over Kang et al. in view of Catt et al. further in view of Yu, applicant argues that the aperture of Kang merely serves as an opening for the sample. Applicant's argument is not persuasive because claim 1 requires a sample application means, which is the aperture situated over the reservoir pad taught by Kang et al. Applicant argues that Catt et al. does not teach a platform flow channel formed from a top and bottom layer and in face to face contact. Applicant's argument is not persuasive because the top layer of Catt et al. (200, Fig. 2) is in fixed face to face contact with the

bottom layer (201, Fig. 2) and the bottom surface contains an indent (201 is indented to hold the membrane, 202, Fig. 2). The top and bottom layers are in face to face contact because the edges of the 201 and 200 in Figure 2 are fixed to each other and the faces of the layers are then connected along the edges. Furthermore, applicant argues against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

4. With respect to the rejections over Kang et al. in view of Catt et al. further in view of Segal et al., applicant argues that Segal et al. fail to cure the deficiencies of Kang et al. and Catt et al. The response to applicant's arguments of the references of Kang et al. and Catt et al. are above.

5. A new ground(s) of rejection is made in view of the addition of new claims 36-39 which include new limitations of open areas to inhibit flow of sample between top and bottom layers and rectangular and cylindrical protrusions in the top layer.

Conclusion

No claims are allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant

to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher L. Chin/
Primary Examiner, Art Unit 1641

/Melanie Yu/
Examiner, Art Unit 1641